

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION See paragraph 2 below

International application No.
PCT/CA2004/000456

International filing date (day/month/year)
26.03.2004

Priority date (day/month/year)
28.03.2003

International Patent Classification (IPC) or both national classification and IPC
C12N5/06, C12N15/11

Applicant
MOUNT SINAI HOSPITAL

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

Authorized Officer



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Nichogiannopoulou, A

Telephone No. +49 89 2399-8054



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/CA2004/000456**JC20 Rec'd PCT/PTO 28 SEP 2005****Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
- 3 ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
- 4 Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000456

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 37, 38 completely and 24, 33-35 in regard to industrial applicability

because:

- ☒ the said international application, or the said claims Nos. 24, 33-35 in regard to industrial applicability relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 37, 38
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000456

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-36

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------------------|
| Novelty (N) | Yes: Claims | 1-7, 9-16, 19-36 |
| | No: Claims | 8, 17, 18 |
| Inventive step (IS) | Yes: Claims | 1-7, 9-16, 19-36 |
| | No: Claims | 8, 17, 18 |
| Industrial applicability (IA) | Yes: Claims | 1-23, 25-32, 36 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/CA2004/000456

Re Item I

JC20 Rec'd PCT/PTO 28 SEP 2005

Basis of the report

1. The basis of this report is the application as originally filed.

Re Item II

Priority

1. The following document was published prior to the international filing date but later than the priority date claimed (P-document):

P1: HOUGH MARGARET R ET AL: "Generation of canine embryonic stem cells for use in animal models of human single gene disorders." BLOOD, vol. 102, no. 11, 16 November 2003 (2003-11-16), page 150b, XP002296801 & 45TH ANNUAL MEETING OF THE AMERICAN SOCIETY OF HEMATOLOGY; SAN DIEGO, CA, USA; DECEMBER 06-09, 2003 ISSN: 0006-4971

2. The priority document pertaining to the present application was not available at the time of establishing this first written opinion. Hence, the current assessment is based on the assumption that all claims enjoy priority rights from the filing date of the priority document (28.03.03). If it later turns out that this assumption is incorrect, P1 will become relevant to the assessment of whether the present application satisfies the criteria set forth in Article 33(2) and (3) PCT.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. No meaningful examination could be performed for claims 37, 38 completely and 24, 33-35 in regard to industrial applicability, for the following reasons:

1.1. Rule 66. 1.(e) (PCT):

No complete international search report has been established for claims 37 and 38 (see Form PCT/ISA/210). Accordingly, said claims need not be the subject of international preliminary examination.

- 1.2. Claims 24 and 33-35 -as far as they concern *in vivo* methods- relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item IV

Lack of unity of invention

The present application discloses the isolation of embryonic stem cells from canine embryos and the establishment of canine embryonic stem cell lines. Primers hybridising to the canine Okt4 sequence are separately disclosed and claimed. The common concept linking the above disclosures is the canine origin of the cells and the sequences respectively. This concept cannot however be regarded as novel. Szabo et al., 1996 disclose canine BRCA1 sequences derived from canine cells.

In the light of the prior art, the problem underlying the present application can be seen as the provision of further canine cells and of further canine sequences.

The solutions as disclosed and claimed in the present application can be summarised in the provision of canine embryonic stem cells and the provision of further sequences hybridising to the canine Okt4 sequence.

Due to the fact that cells and sequences of canine origin are already known from the prior art, due to the essential differences between the claimed cells and sequences and due to the fact that no other technical feature can be distinguished which in the light of the prior art could be regarded as a special, common technical feature, the ISA is of the opinion that there is no single inventive concept underlying the plurality of different inventions of the present application in the sense of Rule 13.2 PCT.

Consequently there is lack of unity, and the different inventions not belonging to a common inventive concept are formulated as the different subjects on the communication pursuant to Article 17(3)(a) PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: DENNING CHRIS ET AL: "New frontiers in gene targeting and cloning: Success, application and challenges in domestic animals and human embryonic stem cells." REPRODUCTION (CAMBRIDGE), vol. 126, no. 1, July 2003 (2003-07), pages 1-11, XP002296813 ISSN: 1470-1626

2. **Novelty and Inventive step** (Article 33(2) and (3) PCT)

- 2.1. The present application discloses the isolation of embryonic stem cells from canine embryos and the establishment of canine embryonic stem cell lines. Canine embryonic stem cells and cell lines have been neither disclosed nor suggested in the available prior art. D1, which is a recent review in the field of animal embryonic stem cells is silent about the existence of embryonic stem cells in canines. Claims 1-7, 9-16 and 19-36 are thus considered to be novel and inventive under the terms of Articles 33(2) and (3) PCT.
- 2.2. Claims 8, 17 and 18 are defined merely by the process they are produced by. It is hereby noted that for a product to be considered novel, the product has to be novel *per se*, irrespective of the method it is obtainable by. It becomes evident that claims 8, 17 and 18 can not possibly be considered novel or inventive under the terms of Article 33(2) and (3) PCT.
3. **Industrial applicability** (Article 33(4) PCT)
- The subject-matter of the claims for which an opinion has been established (see item III) appears to be industrially applicable under the terms of Article 33(4) PCT.